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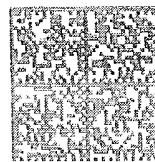
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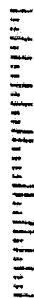
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,613	03/22/2004	Robert F. Casper	58267-CON2(46453)	2635

7590 10/20/2004

Evenson, McKeown, Edwards & Lenahan P.L.L.C.  
Suite 700  
1200 G Street, N.W.  
Washington, DC 20005

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/806,613

Applicant(s)

CASPER ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-22 and 29-34 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-22 and 29-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/22/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Art Unit: 1616

### **First Office Action on the Merits**

#### ***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-22 and 29-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are "use claims" and, thus, are not patentable under 35 USC 101.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19-22 and 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because they merely recite the use of an estrogenically active substance and a progestogenically active substance in the preparation of a medicament without the recitation of steps of how this use is actually practiced.

***Other Matters***


4. The examiner notes the instant claims were previously presented in the parent case (Application No. 10/134,455, now US Patent No. 6,747,019) and were rejected as indicated above. No changes have been made to the original claims.

***Telephone Inquiry***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

<b>FORM PTO-1449</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>			<b>DOCKET NO.:</b> 58267-CON2(46453)		<b>SERIAL NO.:</b> -		
			<b>APPLICANT(S):</b> Robert F. CASPER, et al.				
			<b>FILING DATE:</b> Herewith		<b>GROUP NO.:</b> 1616 (presumed)		
<b>UNITED STATES PATENT DOCUMENTS</b>							
EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
BB	AA	4,957,119	09-18-90	De Nijs	128	832	
	AB	5,088,505	02-18-92	De Nijs	128	830	
	AC	5,108,995	04/28/92	Casper	514	170	
	AD	5,256,421	10/26/93	Casper	514	170	
	AE	5,276,022	01/04./94	Casper	514	170	
	AF	5,382,573	01/17/95	Casper	514	170	
	AG	5,422,119	06/06/95	Casper	514	170	
	AH	5,585,370	12/17/96	Casper	514	170	
	AI	5,633,242	05/27/97	Oettel, et al.	514	170	
BB	AJ	6,133,251	10/17/00	Dittgen, et al.	514	170	
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES/NO
BB	BA	EP 0 309 263	03.29.89	EUROPE	—	—	Yes
	BB	WO 97/11680	04.03.97	WIPO	—	—	Yes
	BC	EP 0 275 716	07.27.88	EUROPE	—	—	Yes
	BD	EP 0 770 388	05.02.97	EUROPE	—	—	Abstract also see U.S. 6,133,251
	BE	DE 44 29 374	02.01.96	GERMANY	—	—	Abstract also see U.S. 5,633,242
BB	BF	WO 98/37897	09.03.98	WIPO	—	—	Yes
<b>OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)</b>							
BB	CA	Lobo, et al., "A novel intermittent regimen of norgestimate to preserve the beneficial effects of 17β-estradiol on lipid and lipoprotein profiles," Am. J. of Obstet. & Gynecol., Vol. 182, No. 1, Part 1, January 2000, pp. 41-49 (XP-000900454).					
	CB	Sulak, et al., "Efficacy and Safety of a Constant-Estrogen, Pulsed-Progestin Regimen in Hormone Replacement Therapy," Int'l. Journal of Fertility and Women's Medicine, Nov-Dec. 1999, pp. 286-296 (XP-000934379).					
	CC	Vanin, et al., "Lumbar vertebral density and mechanical properties in aged ovariectomized rats treated with estrogen and norethindrone or norgestimate," Am. J. of Obstet. & Gynecol., Vol. 173, No. 5, November 1995, pp. 1491-1498 (XP-000934383).					
BB	CD	Christin-Matrick, et al., "Perceptives de la contraception," La Revue du Practicien, 1995, pp. 2449-2453 (English abstract on p. 2453 (last page)).					
<b>EXAMINER:</b> <i>Badio</i>					<b>DATE:</b> <i>10/15/04</i>		